

Sheet 1 of 1

FORM PTB 1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:

CV01490K

APPLICATION NO.:

10/057,339

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

APPLICANT:

T. KOSOGLU, et al.

FILING DATE:

01/25/2002

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1617

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA					
	AB					
	AC					
	AD					
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					
	AK					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES	NO
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

K3	AQ	T. Kosoglou et al., "CoAdministration of Simvastatin and Ezetimibe Leads to Significant Reduction in LDL-Cholesterol", Proceedings of 3 rd International Congress on Coronary, Artery Disease from Prevention to Intervention, Lyon, France p. 71 (2000), XP008027568					
	AR						
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DATE CONSIDERED

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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: CV01490K	SERIAL NO.: 10/057,339
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			APPLICANT: T. Kosoglou, et al.	
			FILING DATE: 01/25/2002	
GROUP: 1614				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
K	AA	Exhibit A: SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary		
K	AB	Exhibit B: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AC	Exhibit C: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AD	Exhibit D: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AE	Exhibit E: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AF	Exhibit F: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AG	Exhibit G: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AH	Exhibit H: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
K	AI	Exhibit 1: Master Sheet for the SCH 58235 and Lovastatin Research Study, <i>Schering-Plough Research Institute</i> (Protocol No. C906-411), page 1576-1585		
K	AJ	Exhibit 2: Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, <i>Peninsular Testing Corporation</i> , page 106-112		
K	AK	Exhibit 3: Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," <i>Schering-Plough Research Institute</i> (Protocol No. C98-010), page 1558-1566		
K	AL	Exhibit 4: Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, <i>Peninsular Testing Corporation</i> , page 124-130		
K	AM	Exhibit 5: Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," <i>Schering-Plough Research Institute</i> , page 1-8		
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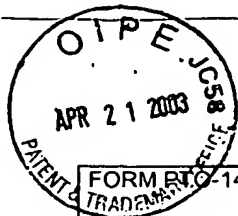
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
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K ₃	FR	WO 96/19450	06/27/96	PCT	C07D	205/08		
K ₃	FS	WO 97/21676	06/19/97	PCT	C07D	205/09		
K ₃	FT	WO 97/41098	11/06/97	PCT	C07D	205/09		
K ₃	FU	WO 00/23415	04/27/00	PCT	C07C	69/734		
K ₃	FV	WO 00/23416	04/27/00	PCT	C07C	69/734		
K ₃	FW	WO 00/23425	04/27/00	PCT	C07D	209/80		
K ₃	FX	WO 00/23445	04/27/00	PCT	C07D	471/12		
K ₃	FY	WO 00/23451	04/27/00	PCT	C07D	487/14		
K ₃	FZ	WO 00/28981	05/25/00	PCT	A61K	31/00		
K ₃	GA	WO 00/31548	06/02/00	PCT	G01N	33/68		
K ₃	GB	WO 00/32189	06/08/00	PCT	A61K	31/415		
K ₃	GC	WO 00/34240	06/15/00	PCT	C07D	205/08		
K ₃	GD	WO 00/37057	06/29/00	PCT	A61K	9/48		
K ₃	GE	WO 00/37078	06/29/00	PCT	A61K	31/44	X(abs.)	
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K ₃	GG	WO 00/38722	07/06/00	PCT	A61K	45/06		
K ₃	GH	WO 00/38723	07/06/00	PCT	A61K	45/06		
K ₃	GI	WO 00/38724	07/06/00	PCT	A61K	45/06		
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K ₃	GY	WO 00/63153	10/26/00	PCT	C07C	69/734		
K ₃	GZ	WO 00/63161	10/26/00	PCT	C07C	237/30		
K ₃	HA	WO 00/63190	10/26/00	PCT	C07D	265/38		
K ₃	HB	WO 00/63196	10/26/00	PCT	C07D	277/04		
K ₃	HC	WO 00/63209	10/26/00	PCT	C07D	471/04		
K ₃	HD	WO 00/63703	10/26/00	PCT	G01N	33/92		



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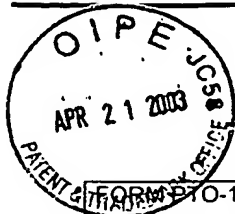
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	HM	WO 00/78313	12/28/00	PCT	A61K	31/422		
	HN	WO 01/00579	01/04/01	PCT	C07D	213/65		
	HO	WO 01/00603	01/04/01	PCT	C07D	277/24		
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	HQ	WO 01/12176	02/22/01	PCT	A61K	31/16		
	HR	WO 01/12187	02/22/01	PCT	A61K	31/404		
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	HY	WO 01/17994	03/15/01	PCT	C07D	413/12		
	HZ	WO 01/18210	03/15/01	PCT	C12N	15/12		
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	IW	WO 02/064130	08/22/02	PCT	A61K	31/195		
	IX	WO 02/064549	08/22/02	PCT	C07C	275/34		
19	IY	WO 02/064664	08/22/02	PCT	C08G	77/02		

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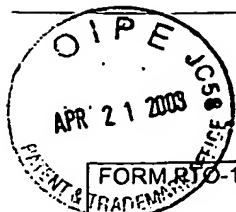
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15	JB	WO 02/26729	04/04/02	PCT	C07D	311/66		
15	JC	WO 02/064094	08/22/02	PCT	A61K			
15	JD	WO 03/018024	03/06/03	PCT	A61K	31/55		
15	JE	WO 03/018059	03/06/03	PCT	A61K	45/06		

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15	JF	Vaccaro, W.D. et al, "Sugar-substituted 2-azetidinone cholesterol absorption inhibitors: enhanced potency by modification of the sugar" <i>Bioorganic & Medicinal Chemistry Ltrs., Oxford, G.B., 8:313-318 (1998)</i>
15	JG	Vaccaro, W.D. et. al., "Carboxy-substituted 2-azetidinones as cholesterol absorption inhibitors", <i>Bioganic & Medicinal Chem. Ltrs. Oxford, G.B. 8:319-322 (1998)</i>
	JH	H. Davis et al., "Ezetimibe, a Potent Cholesterol Absorption Inhibitor, Inhibits the Development of Atherosclerosis in Apo E Knockout Mice", <i>Arterioscler, Thromb. Vasc. Biol</i> 21:2032-2038, (Dec. 2001)
	JI	Simova, E., "Aldol-type addition of hydrocinnamic acid esters to benzylideneaniline", <i>Chemical Abstracts No. 15, 86 (April 11, 1997)</i>
	JJ	Otto et al., "Stereochemistry of dehydration and halogenation of αR^* and αS^* isomeric 3-(α -hydroxybenzyl)-1,4 diphenyl-2 azetidinones, <i>Chemical Abstracts No. 19, 99 (Nov. 7, 1983)</i>
	JK	T. Durst et al, "Metallation of N-Substituted β -Lactams. A Method of the Introduction of 3-substituents into β -Lactams" <i>Canadian Journal of Chemistry</i> , 50:3196-3201 (1971)
	JL	Nobuki, O. et al., "Stereoselective syntheses of β -lactam derivatives by ultrasound promoted Reformatskii reaction" <i>Chemical Abstracts No. 106, 17 (April 27, 1987)</i>
	JM	M. Hoekman, et al., "Synthesis of Homologues of 4,5-Dihydroxy-and 4-Hydroxy-5-oxohexanoic Acid γ -Lactones", <i>J. Agric. Food Chem.</i> , 30:920-924 (1982)
	JN	H. Otto et al. "Darstellung und Stereochemie von 3-(α -Hydroxybenzyl)-1,4-diphenyl-2-azetidinonen", <i>Liebigs Ann. Chem.</i> 1152-1161 (1983)
	JO	G. George et al. "3-(1'-Hydroxyethyl)-2-Azetidinones From 3-Hydroxybutyrates and N-Arylaldimines" <i>Tetrahedron Letters</i> , 26:3903-3906 (1985)
	JP	Hart et al. "An Enantioselective Approach to Carbapenem Antibodies: Formal Synthesis of (+)-Thienamycin", 26 <i>Tetrahedron Letters</i> , 45:5493-5496 (1985)
	JQ	Panfil, I. et al. "Synthesis of β -Lactams from α , β -Unsaturated Sugar δ -Lactones" 24 <i>Heterocycles</i> 6:1609-1617 (1986)
	JR	D. Roger Illingworth, "An Overview of Lipid-Lower Drugs" <i>Drugs</i> 36:63:71 (1988)
	JS	Joseph L. Witztum, M.D., "Current Approaches to Drug Therapy for the Hypercholesterolemic Patient" <i>Circulation</i> 80:1101-1114 (1989)
	JT	B. Ram et al. "Potential Hypolipidemic agents: Part V", 29B <i>Indian J. Chem.</i> 1134-37 (1990)
	JU	Schnitzer-Polokoff, R. et al., "Effects of Acyl-CoA: Cholesterol O-Acyltransferase Inhibition on Cholesterol Absorption and Plasma Lipoprotein Composition in Hamsters" <i>Comp. Biochem. Physiol.</i> 99A:665-670 (1991)
	JV	Horie, M. et al, "Hypolipidemic effects of NB-598 in dogs" <i>Atherosclerosis</i> 88:183-192 (1991)
	JW	Baxter, A., "Squalestatin 1, a Potent Inhibitor of Squalene Synthase, Which Lowers Serum Cholesterol in Vivo", <i>The Journal of Biological Chemistry</i> 267:11705-11708 (1992)
15	JX	Summary Factfile, "Anti-Atherosclerotic Agents" <i>Current Drugs Ltd.</i> (1992)

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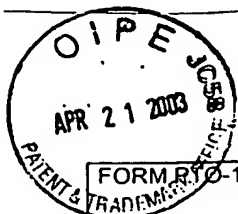
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14	JY	Harwood H. James, "Pharmacologic consequences of cholesterol absorption inhibition: alteration in cholesterol metabolism and reduction in plasma cholesterol concentration induced by the synthetic saponin β -tigogenin cellobioside (CP-88818; tiqueside) 1" <i>Journal of Lipid Research</i> 34:377-395 (1993)
15	JZ	Salisbury, B. et al., "Hypocholesterolemic activity of a novel inhibitor of cholesterol absorption, SCH 48461" <i>Atherosclerosis</i> 115:45-63 (1995)
	KA	Clader, J. W. et al., "Substituted (1,2-Diarylethyl)amide Acyl-CoA;Cholesterol Acyltransferase Inhibitors: Effect of Polar Groups in Vitro and in Viro Activity" <i>Journal of Medicinal Chemistry</i> 38:1600-1607 (1995)
	KB	Sybertz, E., "Sch 48461, a novel inhibitor of cholesterol absorption" <i>Atherosclerosis</i> pp. 311-315 (1995)
	KC	Vaccaro, W, et al, "2-Azetidinone Cholesterol Absorption Inhibitors; Increased Potency by Substitution of the C-4 Phenyl Ring", <i>Bioorg. & Med. Chem.</i> 6:1429-1437 (1998)
	KD	G. Wu et al, "A Novel One-Step Diastereo-and enantioselective formation of trans-azetidinones and its application to the total synthesis of cholesterol absorption inhibitors A.C.S. (4/21/99).
	KE	B. Staels, "New Roles for PPARS in Cholesterol Homeostasis", <i>Trends in Pharmacological Sciences</i> , 22:9 p. 444 (Sept. 2001)
	KF	Abbott et al, "Tricor® Capsules, Micronized", <i>Physicians Desk Reference</i> , January 8, 2001.
	KG	M. Feher et al., 1991, <i>Lipids and Lipid Disorders</i> , p.1-87 (1991).
	KH	M. Ricote et al., "New Roles for PPARs in Cholesterol Homeostasis", <i>Trends in Pharmacological Science</i> , Vol. 22, No. 9 441-443 (2001)
	KI	C. Dujovne et al, "Reduction of LDL Cholesterol in Patients with Primary Hypercholesterolemia by SCH 48461: Results of a multicenter Dose-Ranging Study", <i>J. Clin., Pharm.</i> 41:1 70-78 (Jan. 2001)
	KJ	W. Oppolzer et al., "Asymmetric Diels - Alder Reactions, Facile Preparation and Structure of Sulfonamido - Isobornyl Acrylates", <i>Tetrahedron Letters</i> No. 51, 25:5885-5888 (1984).
	KK	M. Davidson et al., "Colesevelam Hydrochloride: a non-absorbed, polymeric cholesterol lowering agent", <i>Expert Opinion Investigating Drugs</i> , 11:2663-71, (Nov. 2000)
	KL	M. Davidson et al., "Colesevelam hydrochloride (cholestagel): a new, potent bileacid sequestrant associated with a low incidence of gastrointestinal effects", 159 <i>Arch. Intern. Med.</i> 16 1893-900 (Sept. 1999)
	KM	I. Wester, "Cholesterol - Lowering effect of plant sterols", <i>Euro. J.Lipid, Sci. Tech.</i> 37-44 (2000).
	KN	A. Andersson et al., "Cholesterol -lowering effects of a stanol ester-containing low fat margarine used in conjunction with a strict lipid-lowering diet", 1 <i>European Heart. J. Supplements</i> S80 - S90 (1999)
	KO	H. Gylling et al, "Reduction of Serum Cholesterol in Postmenopausal Women with Previous Myocardial Infarction and Cholesterol Malabsorption induced by Dietary Sitostanol Ester Margarine, 96 <i>Circulation</i> 12 4226-4231 (Dec. 16, 1997)
	KP	T. Miettinen et al, "Reduction of Serum Cholesterol with Sitostanol-Ester Margarine in a Mildly Hypercholesterolemic Population", <i>New England Journal of Med.</i> 333 1308-1312 (Nov. 16, 1995)
	KQ	T. Bocan et al., "The ACAT Inhibitor Avasimibe Reduces Macrophages and Matrix Metalloproteinase Expression in Atherosclerotic Lesions of Hypercholesterolemic Rabbits", <i>Arterioscler Thromb Vasc. Biol.</i> 70-79 (Jan. 2000)
16	KR	M. Van Heek et al., "In Vivo Metabolism - Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH 58235, in the Rat and Rhesus Monkey through the identification of the active metabolites of SCH48461," 283 <i>J. Pharma and Experimental Therapeutics</i> 1 157-163 (1997)

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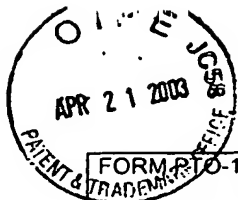
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KS	H. Davis <i>et al.</i> , "The Cholesterol Absorption Inhibitor Ezetimibe Inhibits the Development of Atherosclerosis in apo E knockout (-/-) mice fed low fat and western diets," <i>151 Atherosclerosis</i> 1:133 (July 2000)
KT	L. Nguyen <i>et al.</i> , "Unexpected Failure of Bile Acid Malabsorption to Stimulate Cholesterol Synthesis in Sitosterolemia with Xanthomatosis", <i>10 Atherosclerosis</i> 2, 289-297 (1990)
KU	L. Nguyen <i>et al.</i> , "Regulation of Cholesterol Biosynthesis in Sitosterolemia: effects of lovastatin, Cholestyramine, and dietary sterol restriction," <i>32 J.Lipid Res.</i> 1941-1948 (1991)
KV	M. Cobb <i>et al.</i> , "Sitosterolemia: Opposing Effects of cholestyramine and Lovastatin on Plasma Sterol Levels in a Homozygous Girl and Her Heterozygous Father," <i>45 Metabolism</i> 6 673-679 (June 1996)
KW	M. Huettinger <i>et al.</i> , "Hypolipidemic Activity of HOE-402 is mediated by Stimulation of the LDL Receptor Pathway", <i>13 Arteriosclerosis and Thrombosis</i> 7 1005-1012 (July 1993).
KX	J. Best <i>et al.</i> , "Diabetic Dyslipidaemia", <i>59 Drugs</i> 5 1101-1111 (May 2000)
KY	P. Chong, <i>et al.</i> , "Current, New and Future Treatment in Dyslipidaemia and Atherosclerosis", <i>60 Drugs</i> 1 55-93 (July 2000)
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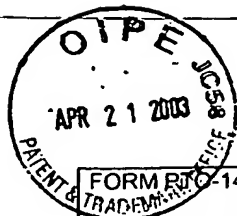
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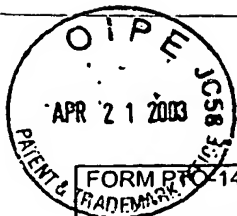
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K	OB	P.F. Belamarich <i>et al.</i> , "Response to Diet and Cholestyramine in a Patient with Sitosterolemia", <i>Pediatrics</i> , 977-981, (December 1990)
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